REMARKS

Claims 1 and 3-9 are pending in the present application. Claims 1, 3 and 7 have been amended. No new claims have been added. It is respectfully submitted that the present amendment raises no new issues nor presents new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendment and following remarks is requested.

I.Objections to Claims 3 and 7

١

Claims 3 and 7 were objected to in the Office Action. Claims 3 and 7 have been amended to correct the typographical errors pointed out by the Examiner. Accordingly, Applicant respectfully requests withdrawal of this objection to the claims.

II.Rejection of Claims 1 - 3 under 35 U.S.C. § 112, Second Paragraph

Claims 1 and 3 were rejected under 35 U.S.C. § 112, second paragraph. Applicant respectfully assert that based upon the above amendment, this rejection is moot.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of this rejection.

III.Rejection of Claims 1 and 3-9 under 35 U.S.C. § 102(b)

Claims 1 and 3 - 9 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Hovancik et al. (US 5,869,471.) Applicant respectfully traverses this rejection as the Hovancik reference does not disclose nor anticipate the invention as claimed.

Hovancik teaches a method of treating arthritis comprising a sixty (60) day treatment period, whereby a phosphonate is administered in combination with an NSAID (non-steroidal anti-inflammatory drug). Hovancik discloses that

"the NSAID active agent and the phosphonate active agent act in synergy. Accordingly, the benefit gained in the treatment of arthritis when utilizing the methods described herein are greater than is seen with either active agent, or their sum, if administered alone. The present methods result in a reduction in the amount of NSAIDS being administered to an arthritic patient, and in addition, also allow a reduction in the dosage of the phosphonate administered over time." (Col. 3, lines 17-25. Also see, col. 3, lines 35-40.)

Hovancik further discloses that within this combination therapy that the phosphonate be administered at least 1 day for every sixty day treatment period. In discussing the 60 day treatment period with respect to the administration of a phosphonate, Hovancik states:

"In addition, a phosphonate must be given at least one day of every sixty (60)-treatment period. For example, a phosphonate may be given every day of said sixty (60)-day treatment period, or given every other day of said sixty (60)-day treatment period or every third day, or

every fourth day, or Day 1 and Day 30, or on Days 1, 10, 20, 30, 45, 60 of said sixty (60)-day treatment period. It may be more desirable to give a phosphonate for the first week at one dose, then switch to another dose for the second, third, and/or fourth weeks. It may be desirable to administer one type of phosphonate on some treatment days, and another type on another treatment day..." (Col. 43, lines 53 to 67.)

Accordingly, it is respectfully asserted that Hovencik does not disclose the use of a phosphonate, either alone or in combination with an NSAID, for a treatment period of <u>more</u> than 60 days.

In contrast, the claims of the present application are directed to a method of treating rheumatoid arthritis in a patient in need of such treatment which comprises intermittently administering an effective amount of a bisphosphonate to the patient, wherein the period between administrations is from 2 months up to about 4 months. Since the treatment period disclosed in Hovencik is limited to a 60 day treatment period, the Hovencik reference does not disclose the longer period between phosphonate administrations as claimed by the instant application.

Therefore, Applicant respectfully asserts that the invention as claimed is not anticipated by Hovencik, because the cited reference does not disclose each and every limitation of the claimed invention. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of claims 1 and 3-9 under 35 U.S.C. § 102(b) over Hovencik.

The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this response or application.

Respectfully submitted,

Novartis Corporate Intellectual Property One Health Plaza, Building 104 East Hanover, NJ 07936-1080 (862) 778-7951

Date:May 16, 2006

Peter J. Waibel Attorney for Applicant Reg. No. 43,228